UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: KIND LLC "HEALTHY AND ALL NATURAL" LITIGATION	15-MD-2645 (NRB) 15-MC-2645 (NRB) Hon. Naomi Reice Buchwald, presiding
This Document Relates to: ALL ACTIONS	

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT KIND LLC'S MOTION TO EXCLUDE THE TESTIMONY AND EXPERT REPORT OF DR. ANTON TOUTOV, PH.D.

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Plaintiffs submit this memorandum in opposition to Defendant KIND LLC's Motion to Exclude the Testimony and Expert Report of Anton A. Toutov, Ph.D.

I. INTRODUCTION

Dr. Anton Toutov is a highly qualified expert in the field of organic chemistry. Plaintiffs retained Dr. Toutov to opine on whether the ingredients in KIND's Products[2] can be considered "natural" from a scientific or chemical perspective. Unlike Defendant's counter-expert, Dr. Hutt, Dr. Toutov is not offering an opinion on an issue of law (interpreting regulations); rather, his opinion relates to his scientific analysis of the ingredients at issue to assess whether they, and products made from them, properly can be characterized as "all natural." He is extraordinarily well-qualified to offer that opinion, which is based on sound science and will be helpful to the trier of fact in this case. KIND's motion to exclude Dr. Toutov's testimony should be denied.

KIND's arguments regarding Dr. Toutov's expertise are wrong. Defendant suggests that Dr. Toutov does not have any prior expertise in FDA regulations, but he does. Toutov Tr. at 28:7-16; Toutov Dec. ¶ 4 at p. 4. KIND contends Dr. Toutov lacks experience in the "food sciences," but this is false, and KIND's counter expert, on whom this argument depends, did not even read Dr. Toutov's scholarly publications or thesis before reaching this conclusion. R56.1 Resp. ¶ 56; Toutov Dec. ¶¶ 2-3, ¶ 4 at pp. 4-5, ¶ 18; Hutt Tr. at 77:5-10. Dr. Toutov's experience and credentials are more than sufficient to qualify him as an expert in this case to opine on the naturalness of the ingredients KIND uses to make its Products.

KIND avoids grappling with Dr. Toutov's actual analysis and conclusions by attacking, instead, the framework he describes for approaching such an analysis. KIND argues that Dr.

[2] "Products" refers to the 39 KIND products listed in Plaintiffs' operative Complaint. *See* ACC ¶ 1.

Toutov "created" the "Elements of Naturalness" framework specifically for use in this case, and that it has "no basis in the relevant scientific, academic or food industry communities." Mtn. Excl. Toutov at 1. However, KIND ignores the fact that Dr. Toutov derived the "Elements of Naturalness" framework through an extensive and inclusive review of all available scientific literature, guidelines, and KIND's own "standards" and "philosophies," all of which he distilled to arrive at the three elements which all of these sources consider critical. Indeed, peer-reviewed, scholarly publications adopt virtually the same approach. Toutov Dec. ¶¶ 7-8. Dr. Toutov did not simply make up this framework.

Fundamentally, however, KIND is wrong to conflate the "elements of naturalness" framework with Dr. Toutov's actual analysis. The framework is simply the organizational structure through which Dr. Toutov presents his analysis, and KIND does not and cannot actually dispute Dr. Toutov's analysis and conclusions. Dr. Toutov's opinions are based upon the application of his expertise in organic chemistry, which he frames using his "Elements of Naturalness" framework, not on the framework itself. And while KIND attacks Dr. Toutov's framework, it cannot actually find fault with the concept that a food's origin, processing, and final form are all important to any consideration of whether or not it can be considered natural.

Dr. Toutov was not retained to define "natural" or to opine on what consumers believe such a label to mean. Rather, he offers an expert, scientific evaluation of whether KIND's Products and, more specifically, the ingredients in them, can be considered "all natural," as KIND represented on its labels. KIND's argument that Dr. Toutov's opinion is not relevant to this litigation because he does not offer a definition of "natural," and does not opine on consumer perception, miss the mark.

Dr. Toutov's vast experience and opinion are highly relevant to the issues in this case, and his expert report and testimony should not be excluded.

II. FACTUAL BACKGROUND

A. Dr. Toutov Is an Expert In Chemistry and Is Qualified to Opine on Whether an Ingredient Can be Considered "Natural"

Dr. Toutov holds a Ph.D. in organic chemistry from California Institute of Technology (Caltech) and worked in the laboratory of a chemistry Nobel Laureate, while holding Natural Sciences and Engineering Research Council, Dow-Resnick, and Bristol Myers-Squibb fellowships. Dr. Toutov has co-founded a number of emerging technology companies, serving as the Chief Science Officer at each. To say that Dr. Toutov is an expert in organic chemistry is an understatement. Defendant's argument in this regard is like saying an astrophysicist is not an expert in math.

One does not need to have a degree in "food science" to have a deep understanding of an experience with the molecules that make up food, how they are derived, and how the human body metabolizes them. In fact, a food science degree may not be the appropriate degree for an expert in this matter, and many pioneers and experts in the science of food did not have food science degrees. It's not the name of the degree that counts, but rather the knowledge and experience conferred.

Dr. Toutov has published original, scholarly, peer reviewed research in the world's most respected scientific journals (e.g., *Nature*, *Journal of the American Chemical Society*) on relevant topics, including heterocycles (a class of molecules that comprise a substantial portion of all volatiles in foods); hydrolysis and hydrogenation of carbon-oxygen bonds (the chemical processes underlying the conversion of starch to syrups, the extraction of raw citrus pectin from fruit, and manufacturing glycerin from fats); industrial refining processes (including refining and processing

of oils; extensive use of hexane and other solvents); synthetic chemistry (relevant to synthesis of small molecules including vitamins), and analytical chemistry (such as use of GC-MS and LC-MS techniques described in the analysis of KIND Products introduced for the first time in this matter as Appendix E to Dr. Hutt's report). Toutov Dec. ¶ 4.

Dr. Toutov has also given presentations on his scholarly scientific research to high profile audiences, including to top-level executives from major food companies such as Clara Foods, Continental Grain, Corteva, Farmers Business Network, Ingredion, Mars, Nestle, Soylent, and Driscoll's. *Id*. Dr. Toutov has also co-founded a number of emerging chemistry technology companies, serving as the Chief Science Officer at each. One of these companies was KorvaLabs, an analytical chemistry company. KorvaLabs performed extensive chemical analyses (including GC-MS and LC-MS) of various kinds of food products (e.g., meats, supplements) as well as many other products, including medicines and human specimens. KorvaLabs also held a Clinical Laboratory Improvement Amendments (CLIA) certification, which is governed by the FDA, CDC, and CMS. *Id*. To say that Dr. Toutov is an expert and experienced in organic chemistry and in the chemistry of food is an understatement.

The fact that Dr. Toutov is not an expert in consumer behavior is irrelevant to his opinions in this case, as he was not retained to provide an expert opinion on what a reasonable consumer would or would not believe. Similarly, previous experience with food labeling in the United States is of no moment, as Dr. Toutov was not retained to provide an expert opinion on food regulations. Indeed, Dr. Toutov considered existing regulations as well as other scientific literature and/or sources of information—including KIND's own "standards" and "philosophies"—in determining the *analytical framework* that he would use to apply his expertise to the issues in this case.

B. Dr. Toutov's "Elements of Naturalness" Framework Serves as a Means Through Which Dr. Toutov Performed His Biochemical Analysis of KIND's Product Ingredients

In making a determination of "naturalness," Dr. Toutov utilized what he describes as the "elements of naturalness" framework. As he describes in his Report, and in his concurrently filed declaration, this approach finds substantial support in the scientific literature, and is a distillation of approaches embodied in current regulations and guidelines.

The first element is the origin of the food product or ingredient. Toutov Rpt. ¶ 32. The threshold inquiry is whether the product or ingredient is found in nature. The second element identified by Dr. Toutov, "Production/Processing," examines the production methods and processing, if any, to which a food or ingredient has been subjected. *Id.* ¶ 33. The final element of naturalness identified by Dr. Toutov examines the final form of the food product—whether, for example, the final form includes artificial or synthetic additives, and whether processing has resulted in "unnecessary and/or undesired molecular addition and/or deletion . . . that distinguishes the consumer product from the raw form of the ingredient/food," and examines the extent and nature of those molecular additions/deletions. *Id.* ¶ 34.

Throughout its Motion, Defendant argues that Dr. Toutov's "Elements of Naturalness" framework is a newly created methodology that Dr. Toutov plucked out of thin air. The truth, in fact, is that Dr. Toutov did not create the "Elements of Naturalness," but rather derived them from the universe of existing literature and regulations, so as to create a framework for analysis based on generally accepted principles concerning "natural" food products. *Id.* ¶ 31; *see also id.* ¶¶ 15-30 (examining alternative regulations and approaches).

These elements should be non-controversial—does KIND really contend that the origin of an ingredient is entirely irrelevant to whether it can be labeled "natural"? The processing that a food or ingredient underwent? The addition of artificial or synthetic additives? Indeed, these

concepts are embodied in the FDA's own publications concerning its potential regulation of the term "natural." *See, e.g.*, Hutt Ex. 5 (80 Fed. Reg. 69,905, 69,908) (inviting comments on potential regulation of "natural" food labels in 2015, and observing that the USDA allows such labels where "[t]he product does not contain any . . . artificial or synthetic ingredient, and (2) the product and its ingredients are not more than minimally processed"); Hutt Ex. 4 (56 Fed. Reg. 60,421, 60,466 (including similar quotation of USDA regulations in FDA's consideration of "natural" labels in 1991)).

Dr. Toutov's "Elements of Naturalness" framework merely served as the structure for Dr. Toutov to provide his expert opinion in a coherent, organized manner that should be relatively non-controversial. Defendant conflates the framework with Dr. Toutov's actual conclusions. Like any other assumption that frames an expert's opinion, the "Elements of Naturalness" provide the conceptual structure for Dr. Toutov's analysis, but his actual analysis and conclusions therefrom do not require or depend on a wider acceptance or adoption of the "elements of naturalness" framework by other published scientists or regulators.

C. Results of Dr. Toutov's Analysis of The Non-Natural Ingredients In KIND's Products

Dr. Toutov's Report sets forth his analysis, in great detail, concerning 15 ingredients that KIND incorporated into the Products, which Dr. Toutov concludes cannot be considered natural. These ingredients are: soy lecithin; soy protein isolate; refined, bleached, and deodorized ("RBD") canola oil; RBD palm kernel oil; RBD sunflower oil; dutch process cocoa; "natural flavors" that include synthetic "carriers"; citrus pectin; starch-converted sugar syrups including glucose syrup, brown rice syrup, and tapioca syrup; vegetable glycerin; synthetic ascorbic acid; synthetic vitamin A acetate; and synthetic D-Alpha Tocopherol Acetate/Vitamin E Acetate. Toutov Rpt. ¶¶ 37-126.

Dr. Toutov's analysis as to each of these ingredients will not be repeated or summarized here but, for example, most of the Products are made with glucose syrup, which "is produced by a multi-step industrial process involving catalytic liquefaction and saccharification of starch," usually derived from GMO corn. Toutov Rpt. ¶ 85; *accord* 21 C.F.R. § 168.120(a) ("Glucose sirup is the purified, concentrated, aqueous solution of nutritive saccharides obtained from edible starch."). Dr. Toutov explains how Canadian regulations, which internal KIND emails reveal the company sought to follow in the absence of regulation by the FDA, prohibit labeling a food made with such an ingredient as "natural," and how KIND's own supplier warns [redacted] Toutov Rpt. ¶ 90 (quoting Hutt Depo., Ex. 13 (Austrade 015)).

Dr. Toutov also explains how soy lecithin, which similarly is used in most of the Products at issue, cannot be considered natural given that:

> It is a highly refined food product, which undergoes a chemical process involving treatment with chemicals, and extensive manipulation through extraction, heating, and purification. A key extraction step typically involves the use of an organic solvent (i.e., hexanes). Hexanes is a class 2 regulated solvent[], is highly toxic to multiple organs, and can be fatal if swallowed or inhaled, posing dangers to operators at refineries that use hexanes during processing.

Toutov Rpt. ¶ 40. Dr. Toutov explains how KIND's own employees appeared to acknowledge that the soy lecithin used in the Products [redacted]. Toutov Rpt. ¶ 43 (footnotes omitted); *see also, e.g.*, Hutt Ex. 7 at KIND_0033925 (KIND's supplier of soy lecithin writes: [redacted]").

Another one of the challenged ingredients is D-Alpha Tocopherol Acetate/Vitamin E Acetate; a synthetic, artificial form of vitamin E that doesn't exist in nature. Toutov Rpt. ¶ 122. Vitamin E Acetate is produced using industrial chemical synthesis and purification techniques,

which includes extraction and purification from seed oils, followed by esterification with an acetic acid equivalent. *Id*. ¶¶ 124. Vitamin E Acetate is not found in nature, is made by synthesis, and cannot be considered "natural." *Id*. ¶ 126. It is listed as an ingredient in certain KIND Products, [redacted]. 56.1 Resp. ¶ 70.

III. LEGAL ARGUMENT

A. Legal Standard

Federal Rule of Evidence 702 permits testimony from a qualified expert if: (1) the expert's knowledge will assist the trier of fact to understand the evidence or determine a fact in issue; (2) the expert bases the testimony on "sufficient facts or data"; (3) the expert's testimony "is the product of reliable principles and methods"; and (4) "the expert has reliably applied the principles and methods to the facts of the case." *Id*. In this regard, Rule 702 incorporates the principles the Supreme Court set out in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999).

The expert's testimony must be "relevant to the task at hand" and must "rest[] on a reliable foundation." *Daubert*, 509 U.S. at 597. Regarding the "relevance" requirement, a court should focus on "whether the proposed expert testimony 'will help the trier of fact to understand the evidence or to determine a fact in issue.'" *A.V.E.L.A., Inc. v. Estate of Marilyn Monroe, LLC*, 364 F. Supp. 3d 291, 325 (S.D.N.Y. 2019) (quoting Fed. R. Evid. 702). Rule 702 embodies a "liberal standard" of admissibility for expert testimony. *See, e.g., Grand River Enters. Six Nations, Ltd. v. King*, 783 F. Supp. 2d 516, 526 (S.D.N.Y. 2011) (quoting *Nimely v. City of New York*, 414 F.3d 381, 395 (2d Cir. 2005)). Regarding the "reliability" requirement, an expert must offer "some explanation as to how the expert came to his conclusion and what methodologies or evidence substantiate that conclusion." *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 127 (2d Cir. 2006), *aff'd*, 552 U.S. 312 (2008). Under *Daubert* "the district court functions as the gatekeeper for expert

testimony." *Raskin v. Wyatt Co.*, 125 F.3d 55, 66 (2d Cir. 1997). "[T]he rejection of expert testimony is the exception rather than the rule." *Cedar Petrochems., Inc. v. Dongbu Hannong Chem. Co.*, 769 F. Supp. 2d 269, 282 (S.D.N.Y. 2011) (quoting Rule 702 advisory committee's note); *Park West Radiology v. CareCore Nat'l LLC,* 675 F. Supp. 2d 314, 327 (S.D.N.Y. 2009) (same); *Fero v. Excellus Health Plan, Inc.*, 502 F. Supp. 3d 724, 749 (W.D.N.Y. 2020) (same). Under the *Daubert* analysis, Dr. Toutov is a highly qualified expert whose testimony is both relevant and necessary to the resolution of the issues in this case.

B. Dr. Toutov Is a Highly Qualified Expert in Organic Chemistry, Which Allows Him to Opine on the "Naturalness" of KIND's Ingredients

Rule 702 states that a witness may be "qualified as an expert by knowledge, skill, experience, training, or education." The Second Circuit has instructed that these words "be read in light of the liberalizing purpose of" Rule 702. *LVL XIII Brands, Inc. v. Louis Vuitton Malletier S.A.*, 209 F. Supp. 3d 612, 636 (S.D.N.Y. 2016) (citing *United States v. Brown*, 776 F.2d 397, 400 (2d Cir. 1985)).

KIND argues that Dr. Toutov is not qualified to opine on food manufacturing or food labeling because he "has no education, experience, or knowledge of food, food manufacturing, and food labeling, and is unfamiliar with the statutory framework for food regulation in the United States." Mtn. Excl. Toutov at 9-10. As an initial matter, Dr. Toutov was retained to provide expert testimony on whether the ingredients in KIND bars can be considered "natural" from a scientific standpoint—an opinion that requires knowledge of the components of food, that is, the synthesis and biosynthesis, structure, function, analysis, properties, behavior, and reactivity of the molecules that make up all food—not topics such as food labeling, the statutory framework for food regulation, or consumer perceptions. Whether a food product or its ingredients can be considered "natural" requires an expert to first establish a working understanding of the term based on the

universe of peer-reviewed research and guidelines and then apply that framework to an analysis of chemical processes each ingredient might undergo before inclusion in Defendant's product. This is exactly what Dr. Toutov did.

One need not be a "food scientist" to have a deep understanding of the chemistry of food on a molecular level, and a food scientist may not have the credentials necessary to offer an opinion on the naturalness of KIND's ingredients depending on their training, knowledge, and experience. A molecule is not different whether it is included in a food, a drug, or some other product. Molecules are (bio)synthesized, extracted, metabolized, modified and/or decomposed according to the same principles of natural law, and to provide expert opinion on these processes, one must have a deep understanding and experience in the physical and natural sciences, a skill set Dr. Toutov clearly possesses. Toutov Rpt. Ex. A; Toutov Dec. ¶ 4. With an award-winning Ph.D. in organic chemistry from Caltech, vast academic and industrial experience in the chemical sciences, his peer-reviewed research focusing on topics such as natural products, synthetic methods, heterocycles, catalysts, industrial chemical processing, and organic synthesis, as well as the emerging technology companies of which he is a co-founder, Dr. Toutov's knowledge, skill, experience, training, and education clearly qualify him to opine on whether ingredients in KIND's Products can be considered "natural" from a biochemical standpoint. Toutov Rpt. ¶¶ 5-6 & Ex. A.

In an attempt to shift the focus away from Dr. Toutov's actual analysis of the ingredients in KIND's Products, KIND argues that Dr. Toutov did not derive the framework for his analysis—the "Elements of Naturalness"—from his experience. Yet, deriving an analytical framework was merely the first step in Dr. Toutov's expert evaluation. However termed, without a clear definition of the term "natural" from the FDA, it was necessary for Dr. Toutov to examine existing definitions and guidance from other regulators and publications in order to frame the analysis of KIND's

products from a chemical perspective. Dr. Toutov reviewed literature and guidance from the FDA, the USDA, the EU, and Canada's CFIA, as well as literature from the scientific community, publications from Whole Foods, dictionary definitions, and KIND's own "standard." Toutov Rpt. ¶¶ 14-35. To suggest that Dr. Toutov did not use his expert knowledge, training, and experience in providing his expert opinion simply ignores the *actual* expert analysis following Dr. Toutov's arrival at an inclusive yet easily digestible definition of "natural"—an analysis derived from his expertise in chemical science (including organic chemistry, biochemistry, inorganic chemistry, and other) and supported in the scholarly literature. *See* Toutov Rpt. ¶¶ 37-126; Toutov Dec. ¶ 5-12.

C. Dr. Toutov's Methodology Is Reliable and Based on the Universe of Peer-Reviewed Analysis in the Scientific Community

Lacking any real basis to attack Dr. Toutov's qualifications, Defendant launches a groundless assault on the methodology Dr. Toutov used in forming his opinions. In doing so, Defendant incorrectly claims that Dr. Toutov's opinions are based solely on his own "unsupported speculation." Mtn. Excl. Toutov at 11. *Daubert* sets forth a non-exclusive list of factors that courts might consider in gauging the reliability of scientific testimony. 509 U.S. at 593-95. These factors are: (1) whether the theory has been tested; (2) whether the theory has been subject to peer review and publication; (3) the known or potential rate of error and whether standards and controls exist and have been maintained with respect to the technique; and (4) the general acceptance of the methodology in the scientific community. *Id*. Whether some or all of these factors apply in a particular case depends on the facts, the expert's particular expertise, and the subject of his testimony. *Kumho Tire*, 526 U.S. at 138. A district court has broad discretion both in determining the relevant factors to be employed when assessing reliability and determining whether that testimony is in fact reliable. *Id*. at 153. The *Daubert* reliability inquiry is "a flexible one" and

"*Daubert* makes clear that the factors it mentions do not constitute a definitive checklist or test." *Kumho Tire*, 526 U.S. at 150 (internal quotations omitted). Despite Defendant's misleading arguments to the contrary, Dr. Toutov's expert opinion satisfies each of the elements established by *Daubert*.

1. Dr. Toutov's Analytical Framework for Determining "Naturalness" Is Testable and Guided by Standards

Defendant has no basis to argue that "no one but Toutov himself would be able to apply" his analytical framework. Mtn. Excl. Toutov at 12. Defendant repeatedly argues that Dr. Toutov did not define natural, but as he testified, "My goal in this matter was not to provide a definition of natural. It was rather to distill acknowledged frameworks and standards into a legible form . . . and then to make evaluations based on those standards." Toutov Tr. at 43:25-44:4; *see also id.* at 44:7-8 ("I'm not providing a definition, rather using known standards to evaluate the claims."). Other experts would be just as capable as Dr. Toutov at applying his analytical framework to an analysis of KIND's products, and if they did so in a "scientifically rigorous" manner, they undoubtedly would reach the same conclusions as he reached. *Id.* at 44:25-45:1. His framework is not subjective in any respect. *Id.* at 45:5-7.

In determining what makes an ingredient "natural," Dr. Toutov reviewed guidelines from the FDA, the USDA, the EU, and Canada's CFIA, as well as literature from the scientific community, publications from Whole Foods, dictionary definitions, research as to consumer perception, and Defendant's own "standard." Toutov Rpt. ¶¶ 14-30. Dr. Toutov determined that all of the sources had three common denominators: a food's origin, its processing, and its final form—what Dr. Toutov refers to as the "Elements of Naturalness." *Id.* ¶¶ 31-35. Under that framework, Dr. Toutov analyzed the KIND product ingredients. And while it is true that a lay

person cannot perform such a scientific product-by-product analysis in this context, an expert in organic chemistry can, and his opinion will assist the trier of fact in this case. Fed. R. Evid. 702(a).

Contrary to Defendant's assertion that Dr. Toutov could not articulate the differences between the three "Elements of Naturalness," Dr. Toutov testified that his analysis of each of the elements differed with each ingredient, and each ingredient must be reviewed on a case-by-case basis. Toutov Tr. at 101:12-23. His report analyzes each ingredient in a clear, objective manner. The difference between each of these elements is obvious. It's the analysis of each element that requires specificity where no bright line rule can exist. *Id*. at 72:16-74:8; *Daubert*, 509 U.S. at 590 (to be scientifically valid, the subject of expert testimony need not be '"known' to a certainty" because, "arguably, there are no certainties in science."). This does not mean that Dr. Toutov is the only person who could apply the framework but, rather, that an expert in organic chemistry can use this same framework to arrive at a determination of whether a given ingredient or food product is "natural."

Defendant argues that as an example of how Dr. Toutov's first element of "naturalness" fails is salt, because when questioned at deposition, Dr. Toutov did not make a sweeping statement that salt was natural. Toutov Tr. at 68:25-69:18. However, Defendant mischaracterizes Dr. Toutov's testimony. In fact, Dr. Toutov testified that minerals are typically not considered natural in the context of "Natural Flavors" where clear guidelines exist, and while there is nothing necessarily unnatural about salt, like any other ingredient, it would require an analysis before making that determination. *Id*. at 121:6-23. Obviously, some salts—like sea salt—originate in nature, while others may not, but "origin" is only one requisite criterion for naturalness. For example, salt may include additives such as anticaking agents, free-flowing agents, or colorants that include synthetic or artificial substances, which would fail the "final form" criterion.

Indeed, Defendant's expert struggled with a similar question at her deposition, ultimately testifying that salt was natural even if something synthetic was added to it, because in her opinion "[redacted]." Hutt Tr. at 82:5-83:20. Clearly, Dr. Toutov's approach to this issue is preferable to Dr. Hutt's, who would consider salt properly labeled "all natural" even if it included a synthetic, carcinogenic additive, so long as that additive appeared in the fine print of the product's ingredient list.

At deposition Defendant also questioned Dr. Toutov about food products such as cheese and bourbon, and whether they were natural under the "Elements of Naturalness" framework, without providing a specific (even hypothetical) ingredient list for each of those products. Again, Dr. Toutov explained that without more information, such a determination of "naturalness" would be incomplete, inappropriate, and would require an inquiry into processing and whether there were unnecessary additives. Toutov Tr. at 115:3-118:20. Indeed, Defendant's line of questioning on this point only underscores Defendant's misunderstanding of Dr. Toutov's analysis. An analysis of bourbon, for example, would be conducted much like an analysis of KIND products. Bourbon does not originate in nature, just as a granola bar does not grow out of the ground. Bourbon is made from a combination of ingredients—corn, yeast and water—that are fermented and distilled. The questions of whether all ingredients are identified in nature (e.g., origin criterion), whether these processes are considered "minimal," (e.g., processing/manufacturing criterion) or whether coloring, flavoring, or other additives have been added (e.g., final form criterion), requires the analysis of an expert in organic chemistry. As Dr. Toutov testified, it is impossible and unscientific to make sweeping generalizations about whether bourbon is "natural" without conducting such an analysis, and he had not analyzed bourbon or any distilled spirit. *Id*.

Defendant's reliance on *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 440 (S.D.N.Y. 2016) ("*Mirena I*"), is misplaced. In *Mirena I*, the party's expert relied only on his tactile senses to make a determination of sharpness and provided no objective standards that could be tested by others. Here, Dr. Toutov has distilled an analytical framework for examining whether an ingredient can be considered "natural" from a scientific standpoint. The fact that the framework—the "Elements of Naturalness"—are all present in the peer-reviewed research and guidelines Dr. Toutov examined, inherently demonstrates that this framework can be employed and tested by others. Indeed, the questions of whether a product originated in nature, whether it was minimally processed, and whether the final form of the ingredient is composed of components that are found in nature, are objective standards capable of application by others.

2. The "Elements of Naturalness" Originate from Research and Guidelines Subjected to Peer Review and Generally Accepted in the Scientific Community

Defendant's argument that the "Elements of Naturalness" framework has not been subjected to peer review and publication is curious given that Dr. Toutov's framework is literally a culmination of *all* of the authoritative peer-reviewed research and guidelines on what it means for something to be "natural." As stated *supra*, Dr. Toutov arrived at the "Elements of Naturalness" by distilling interpretations and guidelines from all of the prominent authorities, literature from the scientific community, and Defendant's own "standard." Toutov Rpt. ¶¶ 14-35. Dr. Toutov did not simply fabricate the elements, but rather, he considered all of the scientific and scholarly literature on the topic of "natural" and identified the core elements they all had in common.

Indeed, peer-reviewed, scholarly publications do adopt virtually the same approach. Toutov Dec. ¶¶ 6-10. Defendant's assertion that Dr. Toutov could not specifically identify articles or publications from which he derived the framework is misleading. Mtn. Excl. Toutov at 13. Dr. Toutov testified that he could not remember off the top of his head which articles set out the three

criteria comprising the "Elements of Naturalness" out of the universe of literature he reviewed, but that the three elements "are certainly found time and again." Toutov Tr. at 64:15-65:18. Moreover, the sources considered by Dr. Toutov in distilling the common elements of "natural" are the subject of an entire section of his report. *See* Toutov Rpt. ¶¶ 14-35. Defendant's argument that the framework is not widely accepted is rather disingenuous given that the framework is so widely accepted, the elements are found in every single source considered and reviewed by Dr. Toutov or by KIND, and KIND itself cannot actually find fault with the concept that an food item's origin, processing, and final form are all important to any consideration of whether or not it can be considered natural.

3. The "Elements of Naturalness" Framework Was Not "Developed" by Dr. Toutov Solely for Use in This Case

Defendant argues that because Dr. Toutov identified the "Elements of Naturalness" for this litigation, his expert opinion should be excluded. Mtn. Excl. Toutov at 14. Indeed, one factor to consider is "whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995). However, Defendant conflates two different aspects of Dr. Toutov's analysis.

In order to provide expert testimony as to the chemical composition and/or alteration of that composition during processing, Dr. Toutov first created a standard framework that is easily understood and common to all of the available literature and guidelines on the topic. However, the framework under which he conducted his analysis is not the subject of his analysis. Dr. Toutov's expertise is organic chemistry, a specialty necessary for the *application* of such an analytical framework to each component of KIND Products. Dr. Toutov's testimony as to the chemical

analysis of each of the ingredients grows naturally and directly out of research he has conducted and regularly conducts, independent of the litigation. *See* Fed. R. Evid. 702 advisory committee's notes to 2000 amendment (citing *Daubert*, 43 F.3d at 1317); Toutov Rpt. ¶¶ 5-8 & Ex. A.

Indeed, for over 10 years, Dr. Toutov's research in this area has been published at the highest levels. *See, e.g.*, Toutov Rpt. Ex. A (Peer-Reviewed Scholarly Publications, including, e.g., Dr. Toutov's 2015 article in *Nature* regarding heterocycles, which account for one quarter of the volatile compounds in food); Toutov Dec. ¶ 4 (discussing same). Yet Defendant's expert, whose sole mission was to discredit Dr. Toutov, admitted that she never even read any of these publications. Hutt Tr. at 77:5-10.

4. Dr. Toutov's Opinions as to the Application of the "Elements of Naturalness" Are Relevant and Based in Science

Defendant finally makes the illogical argument that Dr. Toutov's opinions should be excluded because he could not articulate an objective standard for determining what can be labeled as "natural" and thus his opinion is merely "paid-for say-so." Mtn. Excl. Toutov at 16. Dr. Toutov was not attempting to create a definition of "natural" for the trier of fact to apply; rather, he distilled existing interpretations and guidance for *his own use* as an expert conducting a chemical analysis of certain ingredients used in KIND's Products. And as Dr. Toutov pointed out, it is possible that reasonable minds could differ in their conclusions. That is exactly why parties hire experts, to provide *opinions* that will assist the trier of fact in reaching its ultimate conclusion.

Contrary to Defendant's argument, at deposition Dr. Toutov did not "abandon" his methodology and rely instead on the CFIA's regulatory standards. *Id.* at 7 (citing in large part counsel's own questions, rather than Dr. Toutov's testimony, as support). Rather, Dr. Toutov referred to the CFIA—one of the most comprehensive sets of regulatory guidelines that exists—as one factor he considered in his analysis, in large part because KIND itself sought to adhere to

the CFIA, but he also explained his conclusions "[f]rom a physical chemical perspective." Toutov Tr. at 166:6-18; *see also* Toutov Rpt. ¶¶ 18-21; Toutov Tr. at 168:6-21 (explaining why ion exchange is more extreme than alternative "physical purification processes"); *id.* at 172:6-173:11 (explaining how "hydrolysis is a synthetic chemistry operation in this case").

Defendant's assertion that Dr. Toutov did not apply expert methodology—amounting to *ipse dixit*—is borderline absurd. *See Kewazinga Corp. v. Microsoft Corp.*, No. 18-4500, 2021 WL 4066597, at *23 (S.D.N.Y. Sept. 1, 2021) (describing "the prototypical example of" expert opinion *ipse dixit* as "a conclusion unsupported and unsubstantiated by evidence or methodology," relying instead on speculation, anecdotal evidence, false equivalents, or impertinent evidence). Dr. Toutov's Expert Report contains 54 pages of expert methodology and copious citations to evidence, including Defendant's own documents and deposition testimony. *See* Toutov Rpt. ¶¶ 36-128. Throughout his report, Dr. Toutov painstakingly analyzes each ingredient and changes made to those ingredients on a molecular level, all while referencing scientific studies and/or other scholarly literature as the framework for his analysis. Dr. Toutov's testimony is not *ipse dixit* but, rather, scientific analysis based on his expertise as an organic chemist. *See, e.g.*, *Board of Trustees of AFTRA Ret. Fund v. JPMorgan Chase Bank, N.A.*, No. 09-686, 2011 WL 6288415, at *12-13 (S.D.N.Y. Dec. 15, 2011) ("common-sense factors" derived by expert not *ipse dixit* where expert reviewed and analyzed the guidelines while drawing on relevant experience to inform expert's analysis).

D. Dr. Toutov's Opinion as to Whether KIND's Ingredients are "Natural" Is Clearly Relevant to the Issues in This Case

Defendant contends that Dr. Toutov's expert opinion is not relevant because Dr. Toutov did not establish a definition of "natural" that can be used by a trier of fact to determine if KIND's labeling is deceptive. Mtn. Excl. Toutov at 16. However, Defendant's argument reveals its

fundamental misunderstanding of the purpose of Dr. Toutov's expert opinion. Dr. Toutov did not purport to create a framework for a *consumer* to determine if an ingredient is "natural." Rather, Dr. Toutov established the analytical framework under which he, *as an expert witness*, could evaluate components of KIND Products and the biochemical processes applied to each to determine whether such components are "natural." It is this very aspect—that Dr. Toutov did not leave it to the consumer to decide if a component is "natural"—that renders his expert opinion *necessary* to assist the trier of fact in making that determination.

Similarly, Defendant argues that Dr. Toutov did not provide a definition of what "natural" means to a reasonable consumer or a methodology by which a consumer could determine if KIND's Products are falsely labeled and that, as a result, Dr. Toutov's opinions are of no assistance to the trier of fact in determining whether a reasonable consumer was deceived by KIND's labels. *Id.* at 17. Yet again, consumer perception is not the subject of Dr. Toutov's opinion. As Defendant is well aware, Plaintiffs have retained a different expert, Dr. J. Michael Dennis, to opine on consumer perception. Dr. Toutov's opinion simply analyzes from a scientific standpoint, whether KIND's Products can be considered "natural" because of the components they contain—and his opinion is that they cannot. Dr. Toutov's conclusion that KIND's ingredients are not "natural" is obviously relevant to the issues in this case. *See e.g., Mantikas v. Kellogg Co.*, 910 F.3d 633, 636-37 (2d Cir. 2018) (examining label, in context and "as a whole," to conclude that it "*falsely* impl[ied] that the grain content is entirely or at least predominantly whole grain") (emphasis added).

Finally, Defendant argues that Dr. Toutov's expert opinion is not relevant because he did not consider how KIND's ingredients are actually manufactured, suggesting that Defendant employs processing methods that differ from those examined by Dr. Toutov in his report. Mtn.

Excl. Toutov at 17. Defendant references canola, palm kernel, and sunflower oils as examples.[3] However, as Dr. Toutov explained in his report, KIND uses refined, bleached, and deodorized ("RBD") versions of these oils, which are so heavily processed that they cannot be considered "natural." Toutov Rpt. ¶¶ 51-66. Dr. Hutt could not actually find fault with Dr. Toutov's conclusions regarding the RBD processing these oils undergo, and agreed that RBD processing "[redacted]," which then are added back into these oils "[redacted]." Hutt Tr. at 159:16-160:7. Defendant's expert did not testify that Dr. Toutov's analysis of the oils used by KIND actually was incorrect in any manner.

Even when an oil is mechanically extracted, it still undergoes the degumming, neutralization and bleaching, each of these involving substantial processing. Toutov Rpt. ¶¶ 53, 59, 64. And mechanically extracted oils often undergo hexane extraction after mechanical extraction, to maximize oil yield. Toutov Dec. ¶ 39. Even if Defendant is able to rebut the conclusions drawn by Dr. Toutov's analysis, that would not counsel in favor of excluding the entirety of his Expert Report and testimony on relevance grounds.

IV. CONCLUSION

Dr. Toutov is more than qualified to render an opinion in this matter. He has a deep understanding of and experience with the molecules that make up ingredients in food products

[3] Defendant also suggests that the cocoa powder used in KIND's products is not alkalized and "only some" of the coatings used by KIND use alkalized cocoa powder as a sub-ingredient. As Defendant is essentially arguing that Dr. Toutov's opinion as to the chemical processing of cocoa does apply to "some" of Defendant's ingredients. Moreover, Defendant's own expert Dr. Catherine Adams Hutt could not even identify the proportion of cocoa powder used by KIND that is alkalized versus natural. Hutt Tr. at 179:2-13. In any event, Dr. Toutov never opined that *all* of the cocoa used by KIND is "dutch process" as opposed to "natural." Toutov Rpt. ¶¶ 67-70.

such as the KIND Products. For the foregoing reasons, Defendant KIND LLC's Motion to Exclude Testimony and the Expert Report of Dr. Anton A. Toutov, Ph.D. should be denied.

Respectfully submitted,

Dated: March 4, 2022

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